

EPA Jacket 83100-58



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

83100-58

Date of Issuance:

10/4/19

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

ROTAM ACETOCHLOR 31 % +
MESOTRIONE 3.3%

Name and Address of Registrant (include ZIP Code):

Rotam Agrochemical Company Ltd
c/o Wagner Regulatory Associates, Inc
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin DE, 19707

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Emily Schmid

Emily Schmid, Acting Product Manager 25
Herbicide Branch, Registration Division (7505P)

Date:

10/4/19

ACETOCHLOR	GROUP	15	HERBICIDES
MESOTRIONE	GROUP	27	HERBICIDES

Rotam Acetochlor 31% + Mesotrione 3.3%

An Herbicide for Use in Field Corn, Field Seed Corn, Field Silage Corn, and Yellow Popcorn

ACTIVE INGREDIENTS:

*Acetochlor 31.0%
 **Mesotrione..... 3.3%

OTHER INGREDIENTS: 65.7%

TOTAL: 100.0%

*Contains 2.74 lbs./gal acetochlor

**Contains 0.29 lbs./gal mesotrione

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

HOTLINE NUMBERS

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-Hour Medical Emergency Assistance (Human or Animal), call: **1-800-222-1222**. For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), call CHEMTREC: **1-800-424-9300**.

[Optional referral statements when booklets and container labels are used:

See Panel for First Aid Instructions and booklet for complete Precautionary Statements and Directions For Use.

See label booklet for complete Precautionary Statements, Directions For Use, and Storage and Disposal.

See label booklet for additional Precautionary Statements, Directions For Use, and Storage and Disposal.

See label booklet for complete Directions For Use.]

Sale, use, and distribution of this product in Nassau and Suffolk Counties in the State of New York is prohibited.

ACCEPTED

10/04/2019

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No.

83100-58

Manufactured [For][By]:
Rotam Agrochemical Co. Ltd.
26/F, E-Trade Plaza
24 Lee Chung Street
Chai Wan, Hong Kong

EPA Reg. No.: 83100-LI
EPA Est. No.:

Net Contents: _____ [Gallons/Liters]

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR WEED CONTROL, CROP INJURY, OR ILLEGAL RESIDUES.

NOTE: It is illegal to sell, use or distribute this product within, or into, Nassau County or Suffolk County, New York.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

The following PPE is required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water:

- Protective eyewear
- Coveralls
- Chemical-resistant gloves made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride or viton.
- Shoes and socks

PRODUCT INFORMATION

Rotam Acetochlor 31% + Mesotrione 3.3% is for use in field corn, production seed corn and yellow popcorn. **Rotam Acetochlor 31% + Mesotrione 3.3%** may be used pre-plant, pre-emergence (after planting but before crop emergence), or post-emergence (after crop emergence) in field corn, field seed corn, and field silage corn fields. For yellow popcorn, **Rotam Acetochlor 31% + Mesotrione 3.3%** must be applied before crop emergence (i.e., pre-plant or pre-emergence) or severe crop injury may occur.

Rotam Acetochlor 31% + Mesotrione 3.3% is a combination of the herbicides acetochlor (group 15) and mesotrione (group 27). This combination of herbicide modes of action controls many grass and broadleaf weeds by interfering with normal germination, growth, and seedling development. When applied after weed emergence, **Rotam Acetochlor 31% + Mesotrione 3.3%** will provide control of many broadleaf weed species, but will not provide consistent control of emerged grass weeds. **Rotam Acetochlor 31% + Mesotrione 3.3%** may be used in tank mix combinations with other herbicides registered for use on the above corn crops to enhance or broaden the spectrum of control of weeds listed in the "Weeds Controlled" section of this label.

Applied according to use directions and under normal growing conditions, **Rotam Acetochlor 31% + Mesotrione 3.3%** will not harm the treated crop. During germination and early stages of growth, environmental conditions or other factors that favor poor or slow growth can weaken crop seedlings.

Read and carefully observe precautionary statements and all other information appearing on the labeling of all products used in mixtures and sequential treatments. This label provides specified treatment rates for this product alone and with tank mixtures. Applications which are not consistent with recommendations in this label may result in unsatisfactory weed control, injury to crops, persons, or animals, or other unintended consequences. Refer to specific product labels for crop rotation restrictions and cautionary statements of all products used in these tank mixtures, including precautions on soil pH, sensitive varieties, minimum re-cropping interval, and rotational guidelines. It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture.

Use Restrictions:

- Not for Sale, Sale Into, Distribution and/or Use in Nassau and Suffolk Counties of New York State.
- All containers of **Rotam Acetochlor 31% + Mesotrione 3.3%** must be kept tightly closed when not in use.

Rowland, Grant

From: Schmid, Emily
Sent: Friday, October 04, 2019 7:55 AM
To: Rowland, Grant
Subject: CSF Amendment (EPA Reg. No. 34704-876)
Attachments: [REDACTED]

Hi Grant,

You have a fast track amendment assigned to you for EPA Reg. No. 34704-876. [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

I'm sure this FTA is not even on your radar yet but I still thought I should bring it to your attention for when you get to it.

Thanks,
Emily

Electronic Submission via CDX

June 13, 2018

Document Processing Desk (REGFEE)
ATTN: Reuben Baris, PM 25
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

WRA

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Re: Application to register a new end-use product
Primary Brand Name: Rotam Acetochlor 31% + Mesotrione 3.3% (PRIA R310)

Dear Mr. Baris:

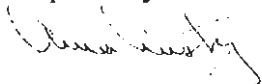
Wagner Regulatory Associates, Inc., as agent for Rotam Agrochemical Company Ltd. is requesting registration of the above referenced end use product containing the previously registered active ingredients acetochlor (PC Code 121601) and mesotrione (PC Code 122990).

In support of this request, the following documents and studies are attached:

- Letter from Rotam Agrochemical Co. Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statements of Formula (8570-4)
- Formulator's Exemption Statement (8570-27)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (internal and public copies) (8570-35)
- Data Transmittal Document
- Data reports as outlined in the Transmittal Document
- Draft labeling
- Certification with Respect to Label Integrity
- A copy of the receipt confirming payment of the required registration fee (PRIA R310, \$5,301)

Thank you in advance for your efforts in reviewing this submission. Please do not hesitate to contact me by email at anna@wagnerreg.com or by phone at 302-510-0039 should you have any questions.

Respectfully submitted,



Anna Armstrong
Agent for Rotam Agrochemical Company Ltd.

Enclosures

2018 JUN 13 10:09

DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**
Rotam Agrochemical Company Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640, 7217 Lancaster Pike, Suite A
Hockessin, DE 19707
EPA Company No. 83100
2. **Regulatory Action In Support Of Which This Package Is Submitted**
Application for Registration
Rotam Acetochlor 31 % + Mesotrione 3.3%
3. **Transmittal Date**
June 13, 2018
4. **List of Submitted Studies**

50595701	Rotam Acetochlor 31% + Mesotrione 3.3% Product Identity and Composition, Description of Materials, Description of Formulation Process, Preliminary Analysis, Discussion of Impurities and Certified Limits; OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750
50595702	Enforcement Method for the Acetochlor Content in Acetochlor 31 % + Mesotrione 3.3% SE, Study No. ARC-RP-INT-233-P-1, OPPTS: 830.1800
50595703	Enforcement Method for the Mesotrione Content in Acetochlor 31 % + Mesotrione 3.3% SE, Study No. ARC-RP-INT-234-P-1, OPPTS: 830.1800
50595704	Physical and Chemical Characteristics of Acetochlor 31 % + Mesotrione 3.3% SE, Study No. ARC-EX-2174-006-P, OPPTS: 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, 830.7100, 830.7300
50595705	Acetochlor 31 % + Mesotrione 3.3% SE: Acute Oral Toxicity- Up-And-Down Procedure in Rats, Study No. 46932, OPPTS: 870.1100
50595706	Acetochlor 31% + Mesotrione 3.3% SE: Acute Dermal Toxicity in Rats, Study No. 46933, OPPTS: 870.1200
50595707	Acetochlor 31 % + Mesotrione 3.3% SE: Acute Inhalation Toxicity in Rats, Study No. 46934, OPPTS: 870.1300
50595708	Acetochlor 31% + Mesotrione 3.3% SE: Primary Eye Irritation in Rabbits, Study No. 46935, OPPTS: 870.2400
50595709	Acetochlor 31% + Mesotrione 3.3% SE: Primary Skin Irritation in Rabbits, Study No. 46936, OPPTS: 870.2500
50595710	Acetochlor 31 % + Mesotrione 3.3% SE: Local Lymph Node Assay (LLNA) in Mice, Study No. 46937, OPPTS: 870.2600
50595711	Rotam Acetochlor 31% + Mesotrione 3.3% Product Chemistry – Group B: Support and Request for Waivers for Certain Physical Chemical Properties Data Requirements; OPPTS 830.6315; 830.6316; 830.6317; 830.6319; 830.6320; 830.6321; 830.7050; 830.7200; 830.7220; 830.7370; 830.7520; 830.7550; 830.7560; 830.7570; 830.7840; 830.7860; 830.7950

Company Name: Rotam Agrochemical Company Ltd.

Company Official: Anna Armstrong
Authorized Agent

Company Contact: Anna Armstrong
Authorized Agent


Signature

(302) 510-0039 / anna@wagnerreg.com
Phone / Email

030619061104



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D448780; **FILE SYMBOL No.:** 83100-LI; **PRODUCT NAME:** Rotam Acetochlor 31% + Mesotrione 3.3%; **DECISION No.:** 541933; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** Rotam Agrochemical Company, Ltd.

DATE OUT: August 28th, 2019

SUBJECT: End Use Product Chemistry Review
Product Name: Rotam Acetochlor 31% + Mesotrione 3.3%

FROM: Kathryn Meyer
Product Chemistry Team
CITAB/RD (7505P)

Kathryn Meyer
9/9/2019

S. Brumaker
9.6.19

TO: Grant Rowland / Reuben Baris, RM 25, Herbicide Branch / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Rotam Acetochlor 31% + Mesotrione 3.3%. In support of the registration application, the registrant has submitted a CSF for basic formulation (dated June 13, 2018), a CSF for alternate formulation 1 (dated June 13, 2018), a CSF for alternate formulation 2 (dated June 13, 2018) and 830 series group A and group B product chemistry data with MRID No's. 50595701, 50595702, 50595703, 50595704, 50595711. CITAB has been asked to determine acceptability of the proposed basic and alternate CSFs and the supporting product chemistry data.

October 5, 2019

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Mesotrione (3.3%); Acetochlor (31.0%)
2. Has the registrant claimed substantial similarity to a registered product?
☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product.
3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No
4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - ☒ Yes – approved for food use; ☐ No.
5. Confidential Statement of Formula(s):
☒ Basic – Dated: 06/13/2018
Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

DP BARCODE No.: D448780; **FILE SYMBOL No.:** 83100-L; **PRODUCT NAME:** Rotam Acetochlor 31% + Mesotrione 3.3%; **DECISION No.:** 541933; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** Rotam Agrochemical Company, Ltd.

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☒ No; ☐ NA

Methanol at > 4%: ☐ Yes; ☒ No; ☐ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☒ No; ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

DP BARCODE No.: D448780; **FILE SYMBOL No.:** 83100-LI; **PRODUCT NAME:** Rotam Acetochlor 31% + Mesotrione 3.3%; **DECISION No.:** 541933; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** Rotam Agrochemical Company, Ltd.

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	50595701
830.1600	Description of materials used to produce the product		X		A	50595701
830.1650	Description of formulation process		X		A	50595701
830.1670	Discussion on the formation of impurities		X		A	50595701
830.1700	Preliminary analysis			X	NA	50595701
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Basic CSF dated 06/13/2018; Alternate CSF 1 dated 06/13/2018; Alternate CSF 2 dated 06/13/2018
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method ¹		X		A	50595702, 50595703

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: D448780; **FILE SYMBOL No.:** 83100-LI; **PRODUCT NAME:** Rotam Acetochlor 31% + Mesotrione 3.3%; **DECISION No.:** 541933; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** Rotam Agrochemical Company, Ltd.

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Off-white liquid with mildly bitter odor	A	50595704
830.6314	Oxidation/Reduction	Non-reactive when in contact with water, 5% ammonium phosphate, or aromatic 100 fluid; temperature increase from 23°C to 30°C (7°C increase) and appearance change when in contact with 5% potassium permanganate after 1 minute; appearance change when in contact with iron powder after 24 hours at 25°C	A	50595704
830.6315	Flammability	Waiver request. Product does not contain ingredients that will self-ignite nor is it highly flammable	W, A	50595711
830.6316	Explodability	Waiver request. Product contains no potentially explosive ingredients	W, A	50595711
830.7000	pH	3.23 at 25°C	A	50595704
830.7100	Viscosity	203 cP at 25°C at 100 speed (shear rate) 158 cP at 39°C at 100 speed (shear rate)	A	50595704
830.7300	Density (units)	1.06 g/cm ³ at 25°C	A	50595704
830.6317	Storage stability Or Accelerated storage stability	An accelerated storage stability and corrosion characteristics study was conducted at 54°C for two weeks. At 14 days, the assay for the technical components showed that the mesotrione component in the formulation degraded and fell below the standard certified limits, likely due	U, I	50595711

DP BARCODE No.: D448780; **FILE SYMBOL No.:** 83100-LI; **PRODUCT NAME:** Rotam Acetochlor 31% + Mesotrione 3.3%; **DECISION No.:** 541933; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** Rotam Agrochemical Company, Ltd.

		to high temperature. It is proposed that a one-year storage stability and corrosion characteristics study be conducted at ambient temperature to support OPPTS 830.6317 for registration of this product as a condition of registration.		
830.6320	Corrosion characteristics or Accelerated corrosion characteristics	An accelerated storage stability and corrosion characteristics study was conducted at 54°C for two weeks. At 14 days, the assay for the technical components showed that the mesotrione component in the formulation degraded and fell below the standard certified limits, likely due to high temperature. It is proposed that a one-year storage stability and corrosion characteristics study be conducted at ambient temperature to support OPPTS 830.6320 for registration of this product as a condition of registration.	U, I	50595711

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP BARCODE No.: D448780; **FILE SYMBOL No.:** 83100-LI; **PRODUCT NAME:** Rotam Acetochlor 31% + Mesotrione 3.3%; **DECISION No.:** 541933; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** Rotam Agrochemical Company, Ltd.

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted/cited for the end-use product and has concluded that:

A. Substantial similarity to the cited product from Product chemistry view point

- ☐ Similar
- ☐ Not similar, give reasons
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

B. Confidential Statement of formula

1. Basic CSF (dated 06/13/2018)
 - ☒ Acceptable
 - ☐ Not Acceptable
 - ☐ Not Applicable

2. Alternate CSF #1 (dated 06/13/2018); Alternate CS #2 (dated 06/13/2018)
 - ☒ Acceptable - #1 & #2
 - ☐ Not Acceptable
 - ☐ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s):
- ☐ Not required
- ☐ Data cited; ☐ Acceptable; ☐ Not Acceptable (give reasons)

D. Group B Product chemistry data

- ☐ Acceptable
- ☐ Not acceptable
- ☒ Acceptable with the exception of Guideline(s): 830.6317 and 830.6320; these guidelines are still in progress as a condition of registration
- ☐ Not required
- ☐ Data cited ; ☐ Acceptable; ☐ Not Acceptable;
- ☐ Waiver requests; ☒ Acceptable; ☐ Not Acceptable (give reasons)

E. Product Label/Draft Label

Recommendations – Yes ☐; No ☒

If yes, give recommendations below:

DP BARCODE No.: D448780; **FILE SYMBOL No.:** 83100-LI; **PRODUCT NAME:** Rotam Acetochlor 31% + Mesotrione 3.3%; **DECISION No.:** 541933; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** Rotam Agrochemical Company, Ltd.

Note: Please add additional remarks if necessary for each section



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 18, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-541933
EPA File Symbol or Registration Number: 83100-LI
Product Name: Rotam Acetochlor 31 % + Mesotrione 3.3%
EPA Receipt Date: 13-Jun-2018
EPA Company Number: 83100
Company Name: ROTAM AGROCHEMICAL COMPANY, LTD.

MS. ANNA ARMSTRONG
WAGNER REGULATORY ASSOCIATES, INC.
ROTAM AGROCHEMICAL COMPANY, LTD.
PO Box 640
HOCKESSIN, DE 19707-0640

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S); INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS; REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY; INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:: PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY; CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: June 13, 2018	EPA Reg No./ File Symbol: 83100-XX	Page 1 of 1
Applicant's/Registrant's Name and Address: Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Acetochlor 31% + Mesotrione 3.3%	
Ingredient: Acetochlor + Mesotrione		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1650, 830.1670	Product Identity, Composition/Description of Materials used to Produce the Product/Description of Formulation Process	50595701	Rotam Agrochemical Company Ltd.	Own	
830.1700	Preliminary Analysis	50595701	Rotam Agrochemical Company Ltd.	Own	
830.1750	Certification of Limits	50595701	Rotam Agrochemical Company Ltd.	Own	
830.1800	Enforcement Analytical Method	50595702 50595703	Rotam Agrochemical Company Ltd.	Own	
830.6302	Color	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6303	Odor	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6304	Physical State	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6314	Oxidation/Reduction	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6315	Flammability	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6316	Explosibility	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6317	Storage Stability	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6319	Miscibility	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6320	Corrosion Characteristics	50595711	Rotam Agrochemical Company Ltd.	Own	
830.7000	pH	50595704	Rotam Agrochemical Company Ltd.	Own	
830.7100	Viscosity	50595704	Rotam Agrochemical Company Ltd.	Own	
830.7300	Density/Relative Density	50595704	Rotam Agrochemical Company Ltd.	Own	
870.1100	Acute Exposure - Oral	50595705	Rotam Agrochemical Company Ltd.	Own	
870.1200	Acute Exposure - Dermal	50595706	Rotam Agrochemical Company Ltd.	Own	
870.1300	Acute Exposure - Respiratory/Inhalation	50595707	Rotam Agrochemical Company Ltd.	Own	
870.2400	Acute Exposure - Primary Eye Irritation	50595708	Rotam Agrochemical Company Ltd.	Own	
870.2500	Acute Exposure - Primary Dermal Irritation	50595709	Rotam Agrochemical Company Ltd.	Own	
870.2600	Dermal Sensitization	50595710	Rotam Agrochemical Company Ltd.	Own	

Signature:	Name and Title: Anna Armstrong, Agent for Rotam Agrochemical Company Ltd.	Date: June 13, 2018
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: June 13, 2018	EPA Reg No./ File Symbol: 83100-XX	Page 1 of 1
Applicant's/Registrant's Name and Address: Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Acetochlor 31% + Mesotrione 3.3%	
Ingredient: Acetochlor + Mesotrione		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1650, 830.1670	Product Identity, Composition/Description of Materials used to Produce the Product/Description of Formulation Process	50595701	Rotam Agrochemical Company Ltd.	Own	
830.1700	Preliminary Analysis	50595701	Rotam Agrochemical Company Ltd.	Own	
830.1750	Certification of Limits	50595701	Rotam Agrochemical Company Ltd.	Own	
830.1800	Enforcement Analytical Method	50595702 50595703	Rotam Agrochemical Company Ltd.	Own	
830.6302	Color	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6303	Odor	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6304	Physical State	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6314	Oxidation/Reduction	50595704	Rotam Agrochemical Company Ltd.	Own	
830.6315	Flammability	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6316	Explosibility	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6317	Storage Stability	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6319	Miscibility	50595711	Rotam Agrochemical Company Ltd.	Own	
830.6320	Corrosion Characteristics	50595711	Rotam Agrochemical Company Ltd.	Own	
830.7000	pH	50595704	Rotam Agrochemical Company Ltd.	Own	
830.7100	Viscosity	50595704	Rotam Agrochemical Company Ltd.	Own	
830.7300	Density/Relative Density	50595704	Rotam Agrochemical Company Ltd.	Own	
870.1100	Acute Exposure - Oral	50595705	Rotam Agrochemical Company Ltd.	Own	
870.1200	Acute Exposure - Dermal	50595706	Rotam Agrochemical Company Ltd.	Own	
870.1300	Acute Exposure - Respiratory/Inhalation	50595707	Rotam Agrochemical Company Ltd.	Own	
870.2400	Acute Exposure - Primary Eye Irritation	50595708	Rotam Agrochemical Company Ltd.	Own	
870.2500	Acute Exposure - Primary Dermal Irritation	50595709	Rotam Agrochemical Company Ltd.	Own	
870.2600	Dermal Sensitization	50595710	Rotam Agrochemical Company Ltd.	Own	

Signature 	Name and Title Anna Armstrong, Agent for Rotam Agrochemical Company Ltd.	Date June 13, 2018
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

31/JAN/2019

MEMORANDUM

Subject: Name of Pesticide Product: Rotam Acetochlor 31% + Mesotrione 3.3%
EPA Reg. No./File Symbol: 83100-LI
DP Barcode: D448779
Decision No: 541933
Action Code: R310
PC Codes: 121601 (acetochlor)
122990 (mesotrione)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

Through: Tracy Keigwin, Acting Acute Toxicology Team Leader *Tracy Keigwin*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Grant Rowland, RM Team 25
Herbicide Branch
Registration Division (7505P)

Applicant: Rotam Agrochemical Co., Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt</u>
Acetochlor	31.0
Mesotrione	3.3
<u>Other ingredients:</u>	<u>65.7</u>
Total:	100.0

ACTION REQUESTED: The Risk Manager requests review of acute toxicity studies submitted for EPA File Symbol 83100-LI.

BACKGROUND: Rotam Agrochemical Co., Ltd. has submitted six acute toxicity studies with MRIDs 505957-05 to -10 to support the registration of the proposed product, Rotam Acetochlor 31% + Mesotrione 3.3%, EPA File Symbol 83100-LI. The submission includes a label, company letter and a Basic CSF, Alternate CSF #1 and Alternate CSF #2 dated June 13, 2018.

GLP: Yes

RECOMMENDATIONS:

1. The six studies with MRIDS 505957-05 to -10 are acceptable to support this registration.
2. The acute toxicity profile for the proposed product, Rotam Acetochlor 31% + Mesotrione 3.3%, EPA File Symbol 83100-LI, is as follows:

acute oral toxicity	IV	acceptable	MRID 50595705
acute dermal toxicity	IV	acceptable	MRID 50595706
acute inhalation toxicity	IV	acceptable	MRID 50595707
primary eye irritation	IV	acceptable	MRID 50595708
primary skin irritation	III	acceptable	MRID 50595709
dermal sensitization	positive	acceptable	MRID 50595710

3. The Basic CSF, Alternate CSF #1 and Alternate CSF #2 submitted for 83100-LI must be accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

LABELING: Based on the toxicity profile, the following are the precautionary and first aid statements for this product:

PRODUCT ID #: 83100-LI

PRODUCT NAME: Rotam Acetochlor 31% + Mesotrione 3.3%

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Avoid contact with skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear: Long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride or Viton.

First Aid:

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing

DATA EVALUATION RECORD

Product Reg. No.: 83100-LI

Product Name: Rotam Acetochlor 31% + Mesotrione 3.3%

1. DP BARCODE: 448779				
2. PC CODES: 121601, 122990				
3. CURRENT DATE: January 31, 2019				
4. TEST MATERIAL: Acetochlor 31% + Mesotrione 3.3% Se (Lot # RWD 8/25/17A; PSL Reference Number 171017-20H; 31% Acetochlor and 3.3% Mesotrione; density 1.005 g/mL; liquid)				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Product Safety Labs Study #46932 January 11, 2018 OCSPP 870.1100; OECD 425	50595705	<p>LD₅₀ Females > 5000 mg/kg</p> <p>Four female Sprague-Dawley derived albino rats were tested at the limit dose of 5000 mg/kg.</p> <p>Mortality: 1/4</p> <p>A limit dose of 5000mg/kg was administered to one female. This animal survived so two additional females received the same dose. One of these animals died so one additional animal was tested. Since this animal survived, no additional animals were tested.</p> <p>One female died within one day of test substance administration. Prior to death, this animal exhibited irregular respiration and ocular discharge. One surviving animal was hypoactive and all surviving animals exhibited irregular respiration, ano-genital staining, nasal discharge and/or reduced fecal volume. The animals recovered from these symptoms by</p>	IV	A

		<p>day 4 and gained weight. Gross necropsy of the decedent revealed discoloration of the lungs and distention of the stomach. No gross abnormalities were noted at necropsy for the three surviving animals.</p> <p>Deviation: From page 9 of the study report:</p> <p>The terminal body weight for one animal was not recorded. We agree with the study author that this deviation had no impact on the overall results of the study.</p>		
<p>Acute dermal toxicity / rat Product Safety Labs Study #46933 January 15, 2018 OCSPP 870.1200; OECD 402</p>	50595706	<p>LD₅₀ > 5000 mg/kg (both sexes)</p> <p>Ten Sprague-Dawley derived albino rats were tested at the limit dose of 5000 mg/kg.</p> <p>All animals survived and gained weight. No clinical signs of toxicity were observed. Dermal irritation (erythema) was noted at all dose sites between days 1 and 5. Desquamation was noted at 2/10 dose sites between days 3 and 13. Hyperkeratosis was noted at one site on days 5 and 6. No gross abnormalities were noted at necropsy.</p>	IV	A
<p>Acute inhalation toxicity / rat Product Safety Labs Study #46934 February 15, 2018 OCSPP 870.1200; OECD 403</p>	50595707	<p>LC₅₀ > 2.07 mg/L (both sexes)</p> <p>MMAD (μm): 3.10 μ GSD: 2.39</p> <p>Ten Sprague-Dawley derived</p>	IV	A

		<p>albino rats were tested at 2.07 mg/L.</p> <p>All animals survived and gained weight. Clinical signs of toxicity included hypoactivity in one male and abnormal respiration and/or ano-genital staining in all rats. The animals recovered from these symptoms by day 8 except for one male that exhibited abnormal respiration through day 14. No gross abnormalities were noted at necropsy.</p>		
<p>Primary eye irritation / rabbit Product Safety Labs Study #46935 January 15, 2018 OCSPP 870.1300; OECD 405</p>	50595708	<p>Three female New Zealand albino rabbits were used in the study.</p> <p>No corneal opacity or iritis were observed. The only positive score observed was for chemosis which was observed in one eye at the one hour scoring only. Scores of 1 (not a positive effect) were noted in all eyes for redness and/or chemosis between days 1 and 7. Discharge (not a positive effect, scores of 1-2) was observed in all eyes at one hour and in one eye at 2 hours. No positive scores were noted at 24 hours. All eyes were free of irritation on day 10.</p> <p>The Maximum Mean Total Score = 8.7 at one hour.</p>	IV	A

Primary dermal irritation / rabbit Product Safety Labs Study #46936 January 11, 2018 OCSPP 870.2500; OECD 404	50595709	PDI = 3.5 Three female New Zealand albino rabbits were used in the study. Well defined erythema and very slight to slight edema were observed at all sites between 30-60 minutes after patch removal and 72 hours. All sites were free of erythema and edema on day 10. Desquamation was noted at all dose sites on day 7. Small dark areas of discoloration were noted at all sites between 48 hours and day 14. Deviation: The study report states on page 11 that desquamation was noted at all dose sites on day 10 and at two sites on day 14. However, Table 3 on page 15 shows the desquamation to be present on day 7 and small dark areas of discoloration to be present at all sites on day 10 and at two sites on day 14. This deviation did not affect the outcome of the study.	III	A
Dermal sensitization/mouse Product Safety Labs rLLNA Study #46937 January 24, 2018 OCSPP 870.2600; OECD 429	50595710	This product is positive for dermal sensitization. % test substance tested 100% SI value* 10.87* *Stimulation Index (SI) > 3 is a positive result. The concurrent positive control study with an SI value = 3.92 is acceptable.	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap, W = Waived



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D448780 FILE SYMBOL No.: 83100-LI (screen) DECISION No.: 541933
PC Code: 122990,121601 Company Name: Rotam Agrochemical Company, Ltd.
FOOD Use: Yes ACTION CODE: R 310 PRODUCT NAME: Rotam Acetochlor 31%+Mesotrione 3.3%

DATE OUT: September 19, 2018

SUBJECT: Completeness Check Screen for an End-Use Product

Product Name: Rotam Acetochlor 31%+Mesotrione 3.3%

FROM: Bruce Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

TO: RM #25, Reuben Baris/Grant Rowland
Herbicide Branch
Registration Division (7505P)

Company Name: Rotam Agrochemical Company, Limited

Active Ingredients: Mesotrione (3.30% a.i.)
Acetochlor (31.0% a.i.)

MRID Nos.: 505957-01, -02, -03, -04 & -11

CONCLUSIONS:

Deficiencies: No

(If there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted.

Group B: All required data submitted.

CSF: Basic CSF dated 13 June 2018; Alternate CSFs (1&2) both dated 13 June 2018

Product label: Yes

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and return to me the corrected deficiencies in response to 10-day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Rotam Agrochemical Company, Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707	EPA File Symbol/Registration Number 83100-XX
	Product Name Rotam Acetochlor 31% + Mesotrione 3.3%
	Date of Confidential Statement of Formula (EPA Form 8570-4) 06/13/2018

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Acetochlor and Mesotrione

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

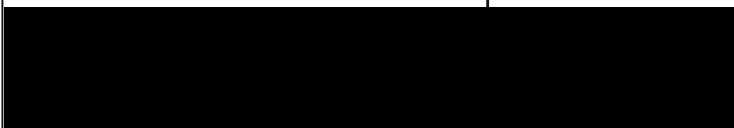


(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Acetochlor		
Acetochlor		
Mesotrione		
Signature	Name and Title Anna Armstrong- Agent for Rotam 	Date 06/13/2018

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Rotam Agrochemical Co.Ltd., c/o Wagner Regulatory Associates, P.O.Box640, Hockessin,DE19707	EPA Registration Number/File Symbol 83100-XX
Active Ingredient(s) and/or representative test compound(s) Acetochlor + Mesotrione	Date June 13, 2018
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food	Product Name Rotam Acetochlor 31% + Mesotrione 3.3%

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

June 13, 2018

Anna Armstrong, Agent

 <p>United States Environmental Protection Agency Washington, DC 20460</p>	<input checked="" type="checkbox"/>	Registration	OPP Identifier Number
	<input type="checkbox"/>	Amendment	
	<input type="checkbox"/>	Other	

Application for Pesticide - Section I

1. Company/Product Number 83100-XX	2. EPA Product Manager Reuben Baris	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Agrochemical Company Ltd. / Rotam Acetochlor 31% + Mesotrione 3.3%	PM# 25	
5. Name and Address of Applicant (Include Zip Code) Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:

Section - II

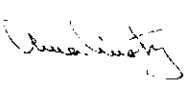
<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
PRIA R310- New End Use Product Registration

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 2.5, 30, 265 gallon, totes, bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other ___adhesive backed label___ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Anna Armstrong	Title Agent for Rotam Agrochemical Company Ltd.	Telephone No. (Include Area Code) (302) 510-0039 (anna@wagnerreg.com)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) DOCUMENTUM
2. Signature 	3. Title Agent for Rotam Agrochemical Company Ltd.		
4. Typed Name Anna Armstrong	5. Date June 13, 2018		

Inert ingredient information may be entitled to confidential treatment

Rowland, Grant

From: Anna Armstrong <Anna@wagnerreg.com>
Sent: Thursday, October 03, 2019 3:32 PM
To: Rowland, Grant
Cc: Anna Armstrong
Subject: RE: EPA reg # 83100-LI
Attachments: 83100-LI label -EPA edits.pdf; 83100-LI.20180613.V2 highlighted.pdf; 83100-LI.20180613.V2 Clean.pdf; 83100-LI- Alt 2 - 3Oct2019.pdf; 83100-LI- Alt 3 - 3Oct2019.pdf; 83100-LI-BasicCSF - 3Oct2019.pdf; 83100-LI- Alt 1 - 3Oct2019.pdf; [REDACTED]-SDS.pdf

Hi Grant,

Thanks again.

Please see the attached revised label (clean and highlighted copies). I believe I captured all of your changes. If not, please let me know.

Also – please see the attached CSFs adding the [REDACTED] as an alternate inert. On CSF Alt 3 I noticed I had [REDACTED] on that one on the attachment – but that shouldn't have been there so I deleted.

Let me know if you have any questions.

Thanks so much and take care,

Anna

From: Rowland, Grant <Rowland.Grant@epa.gov>
Sent: Thursday, October 3, 2019 1:29 PM
To: Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: EPA reg # 83100-LI

Anna,

I am able to review and clear it without sending it off to our inert team so that switch is fine.

-Grant

*Grant Rowland
Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0254*

From: Anna Armstrong <Anna@wagnerreg.com>
Sent: Thursday, October 03, 2019 1:26 PM
To: Rowland, Grant <Rowland.Grant@epa.gov>
Cc: Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: EPA reg # 83100-LI

Hi Grant -

Sorry for multiple emails –but our client had a question just now. They are having difficulty sourcing [REDACTED] and want to know if they can add [REDACTED] as an alternate inert to the [REDACTED] on the CSFs. We know it is an approved inert and have used it in place of [REDACTED] on other CSFs.

I know this is last minute – but if it is possible – let me know. If not – as soon as the approval comes out – I'll submit a notification to add the inert.

Thanks so much and take care!
Anna

From: Rowland, Grant <Rowland.Grant@epa.gov>
Sent: Thursday, October 3, 2019 12:07 PM
To: Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: EPA reg # 83100-LI

Anna,

Thank you for listing the cited products. I have attached the label with EPA comments. If you are able to get an updated label back to me by tomorrow midday(the PRIA is tomorrow), then we can wrap this one up. Thank you.

-Grant

*Grant Rowland
Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0254*

From: Anna Armstrong <Anna@wagnerreg.com>
Sent: Tuesday, October 01, 2019 10:19 AM
To: Rowland, Grant <Rowland.Grant@epa.gov>
Cc: Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: EPA reg # 83100-LI

Hi Grant – we used 524-636 and 62719-693 – but since we submitted tox – I didn't cite any me-too's.

Let me know if this helps.
Thanks and take care,
Anna

From: Rowland, Grant <Rowland.Grant@epa.gov>
Sent: Monday, September 30, 2019 5:29 PM
To: Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: EPA reg # 83100-LI

Hello Anna,
Does this Product have a cited label? Thank you.

-Grant

*Grant Rowland
Herbicide Branch
Registration Division
Office of Pesticide Programs*

From: Anna Armstrong <Anna@wagnerreg.com>
Sent: Monday, August 05, 2019 9:53 AM
To: Rowland, Grant <Rowland.Grant@epa.gov>
Subject: RE: EPA reg # 83100-LI

Hi Grant – I just reached out to our client again and will get back to you asap and before the end of today.
Thanks and take care,
Anna

From: Rowland, Grant <Rowland.Grant@epa.gov>
Sent: Thursday, August 1, 2019 3:09 PM
To: Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: EPA reg # 83100-LI

Hello Anna,

I am writing to inform you that this action is still in our Product Chemistry divisions queue and unfortunately will not be completed by the PRIA due date next Monday (8/5). As of right now, the current estimated completion date for the science review is 9/6/2019. Knowing that, would you and your client be willing to extend the PRIA date another 60 days in order to have the time needed to complete the registration of this action? Please let me know at your earliest convenience. Thank you.

The new PRIA date would be **Friday, October 4, 2019.**

-Grant

*Grant Rowland
Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0254*

From: Anna Armstrong <Anna@wagnerreg.com>
Sent: Friday, April 12, 2019 10:20 AM
To: Rowland, Grant <Rowland.Grant@epa.gov>
Cc: Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: EPA reg # 83100-LI

Hi Grant,
I've heard back from our client – and the season has passed for this year, so they agree to the Aug 5, 2019 revised PRIA timeline for the referenced product.

Thanks very much and have a nice weekend.
Anna

From: Rowland, Grant <Rowland.Grant@epa.gov>
Sent: Thursday, April 11, 2019 2:31 PM

To: Anna Armstrong <Anna@wagnerreg.com>

Subject: EPA reg # 83100-LI

Hello again Anna,

After our last conversation I doubt this one will be much of a surprise. The new Product EP reg # 83100-LI falls under the same situation as the previous action we discussed. Knowing that, can you please discuss with your client the matter of extending this PRIA date out 90 days. The new PRIA date would be Monday August 5th, 2019. Thank you again for your understanding.

-Grant

*Grant Rowland
Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0254*

